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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/626,942	07/25/2003	Colleen Cooper	1653.001US1	7736

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EXAMINER	
ASTORINO, MICHAEL C	

ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 08/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

6

Office Action Summary	Application No.	Applicant(s)	
	10/626,942	COOPER, COLLEEN	
	Examiner	Art Unit	
	Michael C. Astorino	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The applicant has defined **Contemporaneous** on page 2, lines 18-20, "The term 'contemporaneous' denotes times and intervals that are too short or otherwise inconvenient for patients to consult a health-care professional to determine a medication amount for a specific administration." And Applicant has defined **Real time** measurements on page 2-3 as "'Real time' measurements refer to those that can vary significantly over time periods conformable with an interval between successive insulin administrations or boluses, such as a capillary blood glucose test with a glucometer." However, no specific definition of non-realtime measurements has been defined.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15-23 and 25-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In regards to claim 15, it is unclear to the examiner what the applicant intends to claim regarding the last line of the claim "outputting the dosage." It is possible the applicant has intended to mean displaying the dosage to be displayed, or outputting as administering the dosage to the user as a therapy. Dependent claims 16-23 are rejected as being dependent on the rejected claim 15.

In regards to claim 25, it is unclear to the examiner what the applicant is defining as non-real-time diagnostic test, since applicant has provided a definition for "real time", and only provided an example of non-real-time. For purposes of examination, the examiner will assume that the proper definition of non-real-time measurement is any measurement that does not fit within the applicant's definition of real-time. Dependent claims 26-28 are rejected as being dependent on the rejected claim 25.

Note to applicant: The word "for" in the claims may be properly interpreted as "capable of," and "capable of" does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 6-10, and 15-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Surwit et al. US Patent Number 6,024,699 A.

Claim 1. A device for assisting in the personalized treatment of diabetes by a patient, the device comprising:

a memory for storing an individualized reprogrammable management plan for determining dosages of a medication and for storing individualized real-time patient data for use by the plan; (column 8, lines 22-55)

a connection for receiving real-time blood-glucose levels in the patient from a glucometer, to produce a portion of the patient data; (glucometer 26)

an input device for receiving another portion of the patient data directly from the patient (column 7, lines 43-64), the other portion including carbohydrate intake; (The word "for" in the claim may be properly interpreted as "capable of," and "capable of" does not require that reference actually teach the intended use of the element, but merely that the reference does not make it so it is incapable of performing the intended use. Surwit et al. teaches the use of entering diet as patient data. As such, Surwit et al. teaches an input device "for" receiving other portion of patient data including carbohydrate intake.)

a processor for determining a contemporaneous dosage of the medication by applying the individualized plan to at least some of the data in the memory (column 8, lines 22-55),

an output device for returning the dosage (display 22; column 8, lines 22-55);

a communications port for downloading the reprogrammable treatment plan into the memory; (column 9, lines 8-22)

one or more enclosures for the foregoing, in an overall portable package sufficiently small and light to be carried about by the patient. (figure 2)

Claim 2. The device of claim 1 where the memory further stores past patient data. (column 7, lines 28-30)

Claim 3. The device of claim 2 where the past patient data includes past blood-glucose levels. (column 7, lines 43-64 and glucose meter 26)

Claim 6. The device of claim 1 further including a real-time clock for producing time data associable with at least some of the patient data. (column 8, lines 37-39)

Claim 7. The device of claim 1 further comprising a modem for communicating data including at least some of either or both the patient data and the management plan. (column 9, lines 1-29)

Claim 8. The device of claim 1 where the portable package has only a single integral enclosure. (figure 2)

Claim 9. The device of claim 8 where the single enclosure further includes the glucometer. (glucose meter 26)

Claim 10. The device of claim 8 where the single enclosure further encloses a power supply. (Inherent the device has an enclosed power source since the device is portable)

Claim 15. A machine-implemented method for assisting a patient in managing the treatment of diabetes, comprising:

loading a treatment management plan personalized for a particular patient into a device small enough to be carried about by the patient; (figure 2, and column 8, lines 36-55)

measuring a contemporaneous blood-glucose level of the patient (glucose meter 26)

receiving contemporaneous data directly from the patient, at least some of the input data concerning carbohydrate intake (In column 8, line 31, Surwit references to diet as patient data included as a factor for calculating insulin dosage from the algorithm. "Diet" as pertaining to diabetic monitoring at least concerns carbohydrate data);

executing the plan upon a measurement of the condition and upon the received patient data so as to determine an insulin dosage for contemporaneous administration to the patient; (column 8, lines 36-55)

outputting the dosage. (display 22, and column 8, lines 18-63 or Inherent that the diabetic will inject himself or herself with prescribed dosage. Or the amount of insulin, measured by an subsequently injected into the patient by normal operation of insulin injection.)

Claim 16. The method of claim 15 where the contemporaneous blood-glucose level is received directly from a glucometer. (glucose meter 26)

Claim 17. The method of claim 15 further comprising storing past values of at least some of the contemporaneous data. (see column 7, lines 15-67, column 8, lines 1-67 and column 9, lines 1-27)

Claim 18. The method of claim 15 further comprising recalling at least some of the stored contemporaneous data. (see column 7, lines 15-67, column 8, lines 1-67 and column 9, lines 1-27)

Claim 19. The method of claim 15 further comprising receiving history data from the patient. (see column 7, lines 15-67, column 8, lines 1-67 and column 9, lines 1-67)

Claim 20. The method of claim 19 where the history data includes ketone test results. (column 7, lines 42-46)

Claim 21 . The method of claim 15 where the dosage is displayed to the patient for administration. (display 22, column 8, lines 18-55)

Claim 22. The method of claim 15 where the dosage is output directly to a device capable of

administering the medication. The normal operation of a glucose monitoring and medication system is to inject oneself/patient with the proper dosage when glucose readings are not within acceptable levels.

Claim 23. A machine-readable medium bearing instructions and data for carrying out the method of claim 15 on a digital data processor. (PPM 20, column 8, lines 18-35)

Claim 24. A machine-implemented method for assisting a patient in managing the treatment of diabetes, comprising:

storing a template of a management plan for administration of a medication by the patient

entering values of variables in the management plan so as to personalize the plan for the individual patient;

downloading the personalized management plan to a portable device capable of executing the plan in conjunction with other data entered by the patient on a real-time basis in order to determine dosages of the medication on a real-time basis after the download. (see column 7, lines 15-67, column 8, lines 1-67 and column 9, lines 1-27)

Claim 25. The method of claim 24 where at least some of the values of the variables are determined from non-realtime diagnostic tests of the patient. Keeping in mind the applicants definition of "'Real time' as measurement referring to those that can vary significantly over time periods conformable with an interval between successive insulin administrations or boluses, such as a capillary blood glucose test with a glucometer. The examiner's interpretation of a patient

data in column 7, including temperature data is non-realtime data as the applicant has define real-time data since temperature does not vary significantly over time periods conformable with an interval between successive insulin administrations or boluses. Other patient data may include behavioral data or other relevant self-monitoring patient data.

Claim 26. The method of claim 25 further comprising receiving stored patient data from the portable device, and where the management plan is personalized at least partially from the received data. (column 8, lines 37-55)

Claim 27. The method of claim 25 further comprising, after downloading the management plan: (column 8, lines 37-55)

receiving stored patient data from the portable device;

revising the management plan in response to the uploaded data;

downloading the revised plan to the portable device.

Claim 28. The method of claim 25 further comprising receiving uploaded patient data from the portable device over a network. (figure 1, column 7, lines 15-67, column 8, lines 1-67 and column 9, lines 1-27)

Claim 29. The method of claim 24 further comprising displaying at least some of the stored patient data directly to the patient, and receiving revisions to the management plan directly from the patient. (see display 22, column 7, lines 15-67 and column 8, lines 1-67; and column 8, lines

61-63, "The Diacare® instrument adjustment algorithm also guides a patient in 'fine tuning' insulin dosage.")

Claim 30. The method of claim 24 further comprising generating the stored template according to an algorithm for determining dosage of the medication. (column 8, lines 37-55)

Claims 1 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Bortz US Patent Number 5,997,475.

In regards to claims 1 and 14. A device for assisting in the personalized treatment of diabetes by a patient, the device comprising:

a memory (24 memory) for storing an individualized reprogrammable management plan for determining dosages of a medication and for storing individualized real-time patient data for use by the plan;

a connection for receiving real-time blood-glucose levels in the patient from a glucometer, to produce a portion of the patient data; (element number 68, glucose key)

an input device for receiving another portion of the patient data directly from the patient, the other portion including carbohydrate intake; (column 3, lines 65-67 and column 4, lines 1-24)

a processor (22) for determining a contemporaneous dosage of the medication by applying the individualized plan to at least some of the data in the memory (),

an output device for returning the dosage (16);

a communications port for downloading the reprogrammable treatment plan into the memory; (column 3, lines 46-57)

one or more enclosures for the foregoing, in an overall portable package sufficiently small and light to be carried about by the patient. (see figure 1)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. US Patent Number 6,024,699 A as applied to claim 1-3 above, and further in view of Bortz US Patent Number 5,997,475.

In regards to claim 4, Surwit et al. teaches inputting into the system patient data, including data related to diet and past dosage amounts (column 7-8, lines 15-67), as a factor for calculating insulin dosage from the algorithm. "Diet" as pertaining to diabetic monitoring at least concerns carbohydrate data, but Surwit et al. does not particularly state the specific use of inputting past carbohydrate intake. However, Bortz a reference in an analogous art does disclose the specific use of inputting past carbohydrate intake (see abstract). It would have been obvious

to one of ordinary skill in the art at the time the invention was made to modify the diet monitoring data input of Bortz in view of carbohydrate inputs of Bortz, since Bortz states in column 1, lines 16-19, it is useful to be able to track diet, exercise, and medication of the diabetic in order to correctly and effectively determine if any change to the diabetic's therapy will be needed.

In regards to claim 5, the device of claim 4 further comprising programming for presenting patient glucose values with concurrent values of medication dosage and carbohydrate intake. (see Surwit et al., column 7-8, lines 15-67 and figure 9; and Bortz figures 1-2)

Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Surwit et al. US Patent Number 6,024,699 A as applied to claim 1 above, and further in view of Mault et al. US Patent Number 6,790,178 B1.

Surwit et al. teaches glucose meter (26) but does not disclose multiple enclosures associated with the device. However, Mault et al. a reference in an analogous art does disclose the use of "the portable package includes multiple enclosures, the glucometer residing in a separate one of the enclosures." See figure 21, and column 20, lines 38-67 and column 21, lines 1-40; see also figures 1-20 and 22-29 for other enclosures.

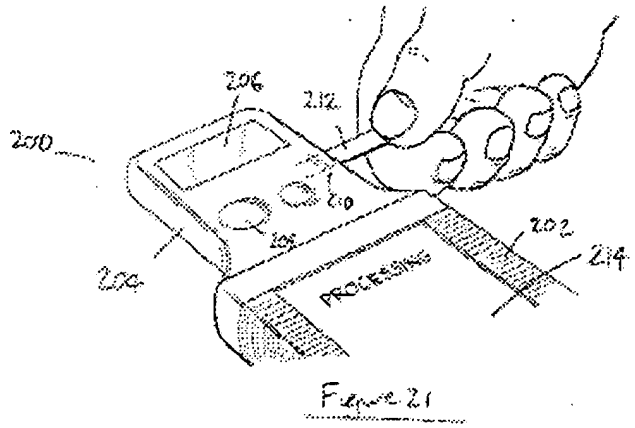


Figure 21

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the PPM of Surwit et al. in view of the multiple enclosures of Mault et al., since Surwit et al. discloses collection of patient data regarding multiple and diverse parameters including blood, breath, bodily fluids and other functions including temperature (column 7, lines 27-30 and lines 42-44, and Mault et al. states a means by which the patient data to be entered into processing computer of the PPM.

Claim 12. The device of claim 11 further including an accessory slot in another one of the enclosures, and where the glucometer communicates with the processor via the accessory slot. (Mault et al., column 20, lines 38-67)

Claim 13. The device of claim 12 where the memory, input device, processor, output device, and accessory slot are located in a personal digital assistant. (PDA 202, Mault et al., column 20, lines 38-67).

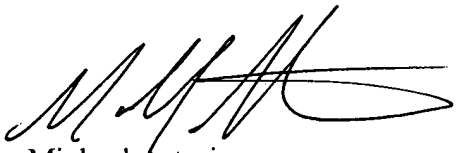
Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. In regards to claim 22, if the applicant intended to recite an automated method of delivering the insulin to the user, see Mann et al. US Patent Number 6,554,798 B1

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Michael C Astorino** whose telephone number is **571-272-4723**. The examiner can normally be reached on Monday-Friday, 8:30AM to 3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Michael Astorino
August 8, 2005